UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TAKEDA PHARMACEUTICALS COMPANY LIMITED and TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., Plaintiffs,	07 Civ. 3844 (DLC)
-v-	OPINION AND ORDER
SANDOZ, INC., Defendant.	

Appearances:

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DENISE COTE, District Judge:

This is the fifth case in a series of related lawsuits filed by Takeda Pharmaceuticals Company Limited and Takeda Pharmaceuticals North America, Inc. (collectively, "Takeda"), against pharmaceutical companies seeking to manufacture generic versions of pioglitazone, a chemical compound used in the treatment of diabetes and for which Takeda holds certain

patents. This Opinion addresses defendant Sandoz's motions for judgment on the pleadings and to dismiss, and Takeda's cross-motion to stay the proceedings. For reasons to be discussed, Sandoz's motions are denied, and Takeda's cross-motion is granted.

BACKGROUND

Takeda owns several patents related to the chemical compound pioglitazone, which is manufactured and sold as the diabetes drug Actos®. Three of these patents are particularly relevant to this case: U.S. Patent No. 4,687,777 (the "'777 Patent"), which covers the chemical compound itself, and U.S. Patents Nos. 5,965,584 (the "'584 Patent") and 6,329,404 (the "'404 Patent"), which cover the combination of pioglitazone with other antidiabetic agents. The '777 Patent is slated to expire in 2011; and the '584 and '404 Patents will expire in 2016, as will the remainder of Takeda's combination-use patents.

The patents are covered by the regulatory framework established under the Hatch-Waxman Act. See Takeda Chem. Indus., Ltd. v. Watson Pharm., Inc., 329 F. Supp. 2d 394, 397-98 (S.D.N.Y. 2004) ("Takeda I"). To date, five generic drug manufacturers, including Sandoz, have filed an abbreviated new drug application ("ANDA") with the Food and Drug Administration ("FDA") seeking to market a generic version of pioglitazone. Takeda has filed suit against each of these manufacturers in

order to protect its patent rights under the Hatch-Waxman Act, alleging patent infringement and inducement of infringement.

In three of those suits, the generic drug manufacturer defendants moved to dismiss certain counts of Takeda's complaints for lack of subject matter jurisdiction or failure to state a claim. Each of these motions to dismiss was denied. See Takeda I, 329 F. Supp. 2d 394; Takeda Chem. Indus., Ltd. v. Ranbaxy Labs., No. 03 Civ. 8250 (DLC), Docket No. 40; Takeda Chem. Indus., Ltd. v. Alphaharm Pty. Ltd, et al., No. 04 Civ. 1966 (DLC), Docket No. 30. Additionally, in two of those suits, the defendant generic drug manufacturer claimed that the '777 Patent was invalid. This challenge was rejected, see Takeda Chem. Indus. v. Mylan Labs, 417 F. Supp. 2d 341 (S.D.N.Y. 2006), and that decision was affirmed by the United States Court of Appeals for the Federal Circuit, see Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007), reh'g and reh'g en banc denied, No. 2006-1329 (Fed. Cir. Sept. 27, 2007). In 2005, the four previous suits were consolidated and, in March 2006, the consolidated cases were stayed so that the parties could revisit their claims closer to the expiration of the '777 Patent in 2011. A status letter is due in January 2009, to set

the stage for the completion of the litigation, which may entail additional discovery to prepare for the trial on these claims.[1]

Sandoz is the fifth generic drug manufacturer to be sued by Takeda over pioglitazone. Sandoz filed a Paragraph III certification with respect to the '777 Patent, indicating that it agreed not to sell pioglitazone until 2011 when the '777 Patent expires. See 21 U.S.C. § 355(j)(2)(A)(vii)(III). It filed Paragraph IV certifications with respect to the '584 and '404 Patents, see 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and Section viii statements with respect to the '584 and '404 Patents, as well as five additional Takeda method-of-use patents for pioglitazone. A Paragraph IV certification asserts that the patent is invalid or will not be infringed by the sale of the generic drug. 21 U.S.C. § 355(j)(2)(A)(vii)(IV). With a Section viii statement, a filer represents that it is not seeking approval for the patented method of use. Id. § 355(j)(2)(A)(viii).

Counts I and II of Takeda's complaint allege infringement and inducement of infringement of the '584 and '404 Patents under 35 U.S.C. § 271(e)(2)(A), which provides that it "shall be an act of infringement to submit [an ANDA] for a drug claimed in

[1] Discovery on Takeda's claims of infringement of its combination-use patents was essentially complete as of the time the trial of those claims was severed from the trial on the validity of the '777 Patent.

a patent or the use of which is claimed in a patent." Under the Hatch-Waxman Act, Sandoz's filing of the Paragraph IV certifications for these two patents required Takeda to file suit within forty-five days of receiving notice of the certifications if it wished to delay FDA approval of the ANDA. See Takeda I, 329 F. Supp. 2d at 397 n.1. Sandoz has challenged these two claims through a Rule 12(c) motion on the ground that it cannot, as a matter of law, induce infringement of these two patents.

Counts III through IX of the complaint allege that Sandoz's sale of pioglitazone will induce infringement of the '584 and '404 Patents as well as other Takeda combination-use patents, in violation of 35 U.S.C. § 271(b). Section 271(b) provides that whoever "actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). The substantive analysis of an infringement claim is the same for each of the counts on which Takeda has sued Sandoz; § 271(e)(2) "simply provides an 'artificial' act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365 (Fed. Cir. 2003).

Takeda seeks both a judgment declaring that Sandoz's making, using, offering for sale, selling, and/or importing

pioglitazone, or inducing such activities, will infringe at least one of Takeda's combination-use patents, as well as a permanent injunction barring these activities. Takeda also seeks a declaratory judgment providing that the effective date of any FDA approval of Sandoz's sale of a product containing pioglitazone be no earlier than the expiration of the last to expire of Takeda's patents.

DISCUSSION

Sandoz does not contest that this Court has subject matter jurisdiction over this action and counts I and II. As a consequence, this Opinion will first address the motion to dismiss each of the claims in this action for its failure to state a claim. It will then address the argument that counts III through IX should be dismissed for lack of subject matter jurisdiction. Finding that each of these motions to dismiss should be denied, the Opinion will conclude with a discussion of Takeda's motion to stay this action due to the substantial evidentiary and legal overlap between it and the four consolidated actions, which are presently stayed.

I. Motions to Dismiss

Sandoz moves to dismiss counts III through IX pursuant to Federal Rule of Civil Procedure 12(b)(6), and for judgment on the pleadings on counts I and II under Federal Rule of Civil

Procedure 12(c).[2] Under the pleading standard set forth in Rule 8(a) of the Federal Rules of Civil Procedure, complaints must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "[A] plaintiff is required only to give a defendant fair notice of what the claim is and the grounds upon which it rests." Leibowitz v. Cornell Univ., 445 F.3d 586, 591 (2d Cir. 2006). Rule 8 is fashioned in the interest of fair and reasonable notice, not technicality, and therefore is "not meant to impose a great burden upon a plaintiff." Dura Pharms., Inc. v. Broudo, 544 U.S. 336, 347 (2005).

When considering a motion to dismiss under Rule 12(b)(6), a trial court must "accept as true all factual statements alleged in the complaint and draw all reasonable inferences in favor of the non-moving party." McCarthy v. Dun & Bradstreet Corp., 482 F.3d 184, 191 (2d Cir. 2007) (citation omitted). The court must apply a "flexible 'plausibility standard,' which obliges a pleader to amplify a claim with some factual allegations in those contexts where such amplification is needed to render the claim plausible." Iqbal v. Hasty, 490 F.3d 143, 157-58 (2d Cir. 2007). In deciding a Rule 12(c) motion, a court must "apply the same standard as that applicable to a motion under Rule

[2] The Rule 12(b)(6) motion was filed first. The Rule 12(c) motion was brought roughly three weeks later.

12(b)(6), accepting the allegations contained in the complaint as true and drawing all reasonable inferences in favor of the nonmoving party." Desiano v. Warner-Lambert & Co., 467 F.3d 85, 89 (2d Cir. 2006) (citation omitted).

A patentee may bring an action for inducing infringement under Title 35, § 271(b) of the United States Code. To establish liability under § 271(b), a patent holder must prove that once the defendant knew of the patent, it "actively and knowingly aid[ed] and abett[ed] another's direct infringement." Water Technologies Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988). "[K]nowledge of the acts alleged to constitute infringement" is insufficient; rather, "specific intent and action to induce infringement must be proven." Warner-Lambert, 316 F.3d at 1363-64 (citation omitted). As noted above, the substantive analysis of an infringement claim under § 271(e)(2)(A) is the same. That provision serves only to create case-or-controversy jurisdiction over an alleged injury that, at the time of the filing of the ANDA, would be merely hypothetical. But, as the Federal Circuit has explained,

> [o]nce jurisdiction is established, however, the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits, including those in a non-ANDA context, the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed.

Id. at 1365.

Takeda has pleaded that Sandoz's seeking approval to sell pioglitazone for use in monotherapy will infringe or induce others to infringe Takeda's combination-use patents, and that approval of Sandoz's ANDA is "substantially likely to result in the commercial manufacture, importation, offer for sale, and/or sale, or inducement thereof, of a drug product which is marketed and sold for use in a method claimed in" its combination-use patents. Specifically, Takeda has alleged that at the time Sandoz filed its ANDA, it was

> aware of the widespread use of pioglitazone in combination therapy; was aware that patients routinely take pioglitazone with a biguanide or an insulin secretion enhancer; and was aware that its customers would know of the use of pioglitazone in combination therapy. Moreover, at the time of the filing of its ANDA, Sandoz manufactured the very products that, when used in combination with pioglitazone, are covered by Takeda's patents: Sandoz sells metformin (a biguanide), covered by the '584 Patent, and glimepride (an insulin secretion enhancer), covered by the '404 Patent.

Further, Takeda has alleged that Sandoz listed generic products on its website and referred customers to a corresponding brand product for further information, and also that (on information and belief) Sandoz's proposed label does not restrict the use of pioglitazone to monotherapy or instruct physicians not to prescribe it in combination with other antidiabetic agents.

These allegations adequately plead a claim for relief under §§ 271(b) and 271(e)(2)(A).

Sandoz claims that DSU Medical Corp. v. JMS Co., Ltd., 471 F.3d 1293 (Fed. Cir. 2006) (en banc), substantially heightened the burden imposed on patent holders to prove inducement of infringement, and that consequently Takeda cannot show the requisite "specific intent," id. at 1306 (citation omitted), to encourage another's infringement as opposed to mere knowledge of the acts alleged to constitute inducement, because its allegations at most show Sandoz's knowledge of possible infringement of Takeda's combination-use patents. Sandoz makes much of the language in DSU Medical Corp. that requires a patent holder to produce "evidence of culpable conduct, directed to encouraging another's infringement, not merely that the inducer had knowledge of the direct inducer's activities." Id.[3] But in DSU Medical Corp., the Federal Circuit reviewed the sufficiency of the evidence of inducement following trial. It did not address the sufficiency of a claim. Applying Rule 8's pleading

[3] Sandoz tries to justify this repetitive motion, in which it essentially rehashes arguments made by three other generic drug companies in their unsuccessful efforts to dismiss Takeda's inducement claims, on the ground that DSU Medical Corp. "has clarified the law concerning actions for inducing infringement." In truth, DSU Medical Corp. explicitly affirmed the Federal Circuit's 1990 articulation of the patent holder's burden in inducement of infringement suits, as stated in Manville Sales Corp. v. Paramount Systems, Inc., 917 F.2d 544, 554 (Fed. Cir. 1990). DSU Medical Corp., 471 F.3d at 1306.

standard, Takeda has given fair notice to Sandoz of its claims that Sandoz has taken and will take acts to induce infringement of Takeda's combination-use patents and has the requisite intent to induce infringement.

Sandoz next argues that as a matter of law its conduct cannot induce infringement of Takeda's combination-use patents. This articulation of its motion to dismiss is another futile effort to impose upon Takeda at the pleading stage a burden that it will not face until it is time for summary judgment motions or trial. The Sandoz arguments require the weighing of evidence and inferences. Whether Takeda will succeed on its claims or is even likely to succeed is beyond the scope of these motions to dismiss.

Sandoz makes one additional argument that is relevant to counts I and II alone. Relying on the Federal Circuit's decisions in Warner-Lambert and Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1332 (Fed. Cir. 2003), Sandoz argues that these counts must be dismissed because a § 271(e)(2) inducement claim must be judged solely on the basis of what Sandoz has requested in its ANDA.[4] Each of these decisions reached the

[4] To support this argument, Sandoz has attached a proposed label for its generic drug, which it has submitted to the FDA for its approval. This label was not available to Takeda when it filed this litigation, it is not properly considered on a motion to dismiss, and Sandoz does not argue in its reply that it is entitled to have it considered.

Federal Circuit after summary judgment was granted by the district court; that is, these decisions do not deal with pleading requirements for the purpose of a motion to dismiss. The instant complaint adequately pleads a claim for a violation of §§ 271(b) and 271(e)(2) based on the contents of Sandoz's ANDA. To the extent it were necessary to reach this issue to resolve this motion to dismiss, the holding of Warner-Lambert that "the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonable be interpreted as an act of infringement (induced or otherwise)" is read to apply only when the request refers "to a patent on an unapproved use." Warner-Lambert, 316 F.3d at 1364-65. Here, the FDA has approved the patented uses of pioglitazone in combination with other therapies, and the specific holdings in Warner-Lambert and Allergan do not control. A careful application of their holdings is particularly warranted given the disagreement with the decisions expressed by members of the Federal Circuit bench. See Allergan, 324 F.3d at 1334 (Schall, J., and Clevenger, J., concurring).[5]

[5] To the extent other district courts have read Warner-Lambert and Allergan more expansively, this Court respectfully declines to do so. See Aventis Pharma Deutschland GmbH v. Cobalt Pharms., Inc., 355 F. Supp. 2d 586 (D. Mass. 2005); ICN Pharms., Inc. v. Geneva Pharms. Tech. Corp., 272 F. Supp. 2d 1028 (C.D. Cal. 2003).

In essence, Sandoz asks for a ruling that a generic drug manufacturer cannot induce infringement of combination-use patents as a matter of law after the principal patent has expired. It cites no authority for this proposition. To the extent Takeda's combination-use patents survive challenges to their validity, then those patents will be entitled to the full protection granted by § 271(b). On the other hand, Takeda will not be entitled to a de facto extension of the life of the '777 Patent through frivolous § 271(b) claims premised on the theory that its combination-use patents are being infringed. Judgment on the merits of these issues, however, must await the completion of discovery, summary judgment, and/or trial.

II. Justiciability

Sandoz moves to dismiss counts III through IX on the ground that they concern only speculative activity that will not occur any earlier than 2011, when the '777 Patent on the pioglitazone chemical compound expires. On a motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), "[t]he plaintiff bears the burden of proving subject matter jurisdiction by a preponderance of the evidence." Aurecchione v. Schoolman Transp. System, Inc., 426 F.3d 635, 638 (2d Cir. 2005). A court must "accept as true all material factual allegations in the complaint," Shipping Fin. Serv. Corp. v. Drakos, 140 F.3d 129, 131 (2d Cir. 1998) (citing Scheuer v.

Rhodes, 416 U.S. 232, 236 (1974)), but refrain from "drawing from the pleadings inferences favorable to the party asserting [jurisdiction]," APWU v. Potter, 343 F.3d 619, 623 (2d Cir. 2003) (citation omitted). "[A] district court may properly dismiss a case for lack of subject matter jurisdiction under Rule 12(b)(1) if it lacks the statutory or constitutional power to adjudicate it." Aurecchione, 426 F.3d at 638 (citation omitted). The inquiry is distinct from whether the plaintiff can state a claim for relief. Carlson v. Principal Fin. Group, 320 F.3d 301, 305-06 (2d Cir. 2003).

This identical argument regarding justiciability has previously been considered and rejected in this litigation. In Takeda I, Watson argued that no case or controversy existed because any alleged infringement of the patents at issue would occur in the future –- that is, when the exclusivity period for the patents would expire. This argument was rejected primarily on the basis of the Federal Circuit's pronouncement that "[a] claim of induced infringement . . . filed prior to the occurrence of direct infringement, does not violate the case or controversy requirement of Article III," Allergan, 324 F.3d at 1332, and Takeda's demonstration that Watson had taken "concrete steps . . . with the intent to conduct activity that would induce infringement," Takeda I, 329 F. Supp. 2d at 402 (citation omitted). Further, Watson "disingenuous[ly]" argued that,

"since it is not challenging the validity of the '777 patent, the earliest it could market its generic pioglitazone is 2011, making Takeda's lawsuit 'speculative' and not ready for adjudication." Id. This argument was rejected because Watson had "reserved the right to market generic pioglitazone as soon as it receives FDA approval." Id. at 402-03.

Sandoz identifies two reasons, however, why its claims differ from those rejected in Takeda I. First, Sandoz observes that at the time Takeda I issued, the viability of the '777 Patent was unclear, as it was being challenged by two generic drug manufacturers. As noted above, the '777 Patent has since been upheld, and that decision was affirmed by the Federal Circuit. Sandoz claims that by filing a Paragraph III certification with respect to the '777 Patent, it has agreed not to sell pioglitazone until the '777 Patent expires in 2011 and has thus confirmed that it cannot commit any acts of direct infringement.

Contrary to Sandoz's argument, the upholding of the '777 Patent does nothing to make Takeda's allegations less timely or concrete. If anything, the fact that the '777 Patent is enforceable but will expire in 2011, only four years from now, makes the dispute between these two parties more concrete and susceptible to adjudication. Just as in Takeda I, Takeda in this case has alleged that Sandoz "has taken significant steps

towards manufacturing and testing its generic pioglitazone products." Takeda I, 329 F. Supp. 2d at 402. Takeda has alleged that Sandoz "has both the capability and intent to offer for sale or sell pioglitazone immediately upon FDA approval" and that "there is nothing in Sandoz's proposed label that would restrict the use of its generic pioglitazone product to monotherapy." Moreover, Sandoz's label "does not state that it may not be used for combination therapy." The reasoning of Takeda I does not lose any of its force in light of the upholding of the '777 Patent's validity. Takeda has alleged an inducement claim of "sufficient immediacy and reality." Long v. Pacific Marine and Supply Co., Ltd., 895 F.2d 761, 765 (Fed. Cir. 1990) (citation omitted).

Second, Sandoz contends that because there is no guarantee that it will sell pioglitazone, this controversy is not ripe for resolution. Sandoz emphasizes that it has not yet obtained FDA approval for its sale of pioglitazone; that it has not made the final business decision to enter the market for the drug; and that the general prescribing practices that will exist in 2011 are unknown. Takeda, however, has shown that Sandoz has taken sufficient action in preparation for an entry into the market to create a dispute that is "definite and concrete," that touches "the legal relations of parties having adverse legal interests," and that is "real and substantial." MedImmune, Inc. v.

Genentech, Inc., 127 S.Ct. 764, 771 (2007) (citation omitted). The motion to dismiss seven claims for lack of subject matter jurisdiction over them is denied.

III. Takeda's Cross-Motion to Stay

Takeda claims that because of the substantial evidentiary and legal overlap between this action and the four actions presently consolidated and stayed before this Court, the instant action should be stayed. It claims that the counts of the complaints asserting the combination-use patents against all five defendants are nearly identical, and that evidence relating to the use of pioglitazone will be both important and substantially the same in all cases, as will the law governing patent infringement and inducement of infringement. Sandoz pointedly observes that Takeda filed its lawsuit against Sandoz and then immediately sought a stay of that lawsuit. But in opposition to Takeda's motion, Sandoz essentially reiterates the arguments made in its substantive motions to dismiss and for judgment on the pleadings.[6]

[6] Sandoz has filed a submission indicating that it wants a ruling on its motions to dismiss and for judgment on the pleadings so that it can deprive the other generic drug defendants of the 180-day exclusivity period to which one or the other of them would otherwise be entitled under the Hatch-Waxman Act. See 21 U.S.C. § 355(j)(5)(B)(iv)(I)-(II). Two of those defendants, Mylan and Ranbaxy, have objected, and have requested a stay of Sandoz's motions. Because this Opinion has denied Sandoz's two motions, Sandoz will not be able to leap over

Courts in this Circuit must balance five factors when considering whether to stay civil proceedings:

> (1) the private interests of the plaintiffs in proceeding expeditiously with the civil litigation as balanced against the prejudice to the plaintiffs if delayed; (2) the private interests of and burden on the defendants; (3) the interests of the courts; (4) the interests of persons not parties to the civil litigation; and (5) the public interest.

Kappel v. Comfort, 914 F. Supp 1056, 1058 (S.D.N.Y. 1996). Applying these factors to the facts of the instant case, it is clear that a stay is warranted.

The substantial similarities between the five cases militate in favor of their simultaneous resolution on the merits. The plaintiff's interest in prosecuting the five actions simultaneously is clear, and the prejudice to Takeda from having to prosecute two nearly identical actions separately is evident. Moreover, Sandoz's protestations notwithstanding, a stay of this action might redound to its benefit as well, as changes in circumstances over the next four years "could even eventually obviate the need for further litigation altogether," as was observed in the consolidation order. As the Order staying the consolidated cases stated, "in addressing the Combination Use Patents it will be necessary to make factual determinations, such as the prescription practices of physicians

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either Mylan or Ranbaxy and obtain an unfair advantage in bidding for the 180-day exclusivity period.

that treat diabetes, that may change over time." This is no less true for the claims at issue in the instant case, and thus this reasoning applies with equal force here. Finally, no prejudice will be wrought on Sandoz as, pursuant to its own representations, it is unable to advance its pioglitazone-related activities until the '777 Patent expires in 2011.

The court's interest in judicial economy should be plain. The relevant non-parties to this action –- the four defendant generic drug manufacturers in the consolidated actions –- will benefit from a stay because simultaneous resolution of all claims will preclude Sandoz, the last of the five generic manufacturers to file an ANDA with respect to pioglitazone, from leapfrogging over them and becoming the first to reach final resolution of Takeda's claims against it. Finally, the public has an interest in the judicial economy wrought by a stay. Accordingly, Takeda's cross-motion to stay the instant action is granted.

CONCLUSION

Sandoz's July 20, 2007 motion for judgment on the pleadings with regard to counts I and II, and its June 28 motion to dismiss counts III through IX, are denied. Takeda's July 27 cross-motion to stay the proceedings is granted. Takeda may restore its claims to this Court's active calendar by letter

application. Further, a status letter from Takeda is due on January 9, 2009.

SO ORDERED:

Dated: New York, New York
October 9, 2007

DENISE COTE
United States District Judge

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